U.S. Patent Application No. 09/752,656
Request for Reconsideration dated January 19, 2006
Reply to Office Actions dated October 19, 2005
and November 21, 2005

REMARKS/ARGUMENTS

Reconsideration and continued examination of the above-identified application are respectfully requested.

The arguments made in the responses filed on October 25, 2005, April 13, 2005, and August 6, 2004 are incorporated herein by reference.

Rejection of claims 1, 3-5 and 8-11, under 35 U.S.C. §102(b) over Maley et al.

At page 2 of the Office Action, the Examiner rejected claims 1, 3-5, 8-11, and 41 under 35 U.S.C. §102(b) as being anticipated by Maley et al. (U.S. Patent No. 5,770,028). The Examiner alleged that Maley et al. describes an electrochemical-sensing apparatus comprising conductive modified particles, such as electrically-conducting carbon or graphite powder particles, having at least one organic group, such as an immobilized enzyme, attached to the particles. The Examiner alleges that any suitable carbon or graphite powder that readily permits the subsequent immobilization of an enzyme may be used to form the active layer. The Examiner further alleges that the carbon particles comprise organic functional groups, such as carboxylate, amino and sulfur-containing functional groups on their surface. The Examiner further alleges that Maley et al. teaches the use of an electrical measuring apparatus for performing sensor response measurements. Regarding claims 4, 5, 9, and 11, the Examiner alleges that Maley et al. teaches the use of carbon black materials, which the Examiner alleges are well known in the art to be pigment materials and that the carbon particles may include a metal substrate layer coating comprising platinum. Regarding claim 8, the Examiner alleges that Maley et al. describes an aggregate having a carbon phase (carbon or graphite particles) and a metal-containing phase (a

finely divided platinum group metal either deposited or adsorbed onto the carbon or graphite particles). The Examiner further takes the position that Maley et al teach all of the positively recited structural limitations of the claimed apparatus. For the following reasons, this rejection is respectfully traversed.

The Examiner included claim 41 in this rejection. However, claim 41 was cancelled in the Amendment dated September 2, 2005.

The present invention as defined in independent claim 1 relates to a sensor for detecting the presence of an analyte in a fluid. The sensor comprises a layer comprising conductive modified particles, wherein the sensor is electrically connected to an electrical measuring apparatus. As explained in the present specification on page 4, line 20 through page 6, line 19, and as specified in claim 1, the layer comprising conductive modified particles has a preexisting resistance that is altered in the presence of the analyte. As explained, for example on page 2, lines 27-29 of the present application, an advantage of the present invention is that it allows for a greater change in resistance, that is, a greater sensitivity of a sensor to the presence of an analyte.

Maley et al., on the other hand, is directed to a completely different type of sensor, which operates on a completely different principle than the sensor of the present invention, and which, contrary to what is alleged by the Examiner, does not contain all of the structural limitations of claim 1. As previously noted, Maley et al. describes a glucose sensor that enzymatically converts glucose to hydrogen peroxide, which transfers electrons to an electrode, thereby directly generating a flow of current that is proportional to the amount of glucose that was present (see, for example col. 1, line 63 to col. 2, line 15 of Maley et al.). Any conductive particles that are described in Maley et al. are merely conductive support particles for the active layer enzyme on

the working electrode (see col. 2, line 64 to col. 3, line 52 and col. 13, line 65 to col. 15, line 63 of Maley et al.).

The Examiner is requested to note that this difference between the sensor of claim 1 and the device of Maley et al. is not just a difference in function, as alleged by the Examiner but a difference in structure as well. The requirements in claim 1 that the "layer comprising conductive modified particles has a preexisting resistance that is altered in the presence of an analyte" and that the sensor includes "an electrical measuring apparatus electrically connected to the layer comprising conductive modified particles that detects an alteration in the preexisting resistance of the layer in the presence of the analyte" necessarily require that the layer have a structure such that when the layer is in the presence of an analyte, its resistance is changed and require that the structure of the electrical connection between the electrical measuring apparatus and the layer be such that the alteration of resistance of the layer in the presence of the analyte can be measured. Maley et al. not only does not teach or suggest the function of the sensor of the present invention, but also does not teach a structure that is capable of performing this function. Specifically, the working electrode of Maley et al. does not include a layer that has a preexisting resistance that is altered in the presence of an analyte and does not teach an electrical measuring device that is connected to the layer in such a way that it is capable of measuring changes in the resistance of the layer. Maley et al. only shows an active layer 96 deposited on a conductive strip 66 (See Fig. 10 of Maley et al.). This configuration does not have the physical capability of detecting an alteration of the resistance of the layer in the presence of an analyte. Accordingly, Maley et al. does not teach or suggest the structure of the sensor claimed in claims 1, 3 - 5, and 8 - 11.

Also, with respect to the Examiner's assertion that the platinum deposited on the carbon

particles is "equivalent" to the aggregate comprising the carbon phase and a metal-containing species phase, applicants respectfully disagree. First, as stated at page 10, line 3 of the present application, an aggregate comprising the carbon phase and a metal-containing species phase is described in U.S. Patent No. 6,017,980, which is incorporated in the application in its entirety by reference. This patent describes an aggregate having a carbon phase and a metal-containing species phase as an aggregate which essentially is a co-fumed product of carbon and metal which forms an aggregate. U.S. Patent No. 6,017,980 specifically states that the aggregate is not a separate mixture of carbon black and metal particles. To the contrary, the aggregate is an aggregate having regions of a carbon phase(s) and metal-containing species phase(s) within the same aggregate. Clearly, this is not shown in Maley et al. At col. 14, beginning at line 11, Maley et al. clearly teaches that the platinum is merely deposited on top of the carbon particles and clearly would not be a co-fumed product. There would be no carbon phase or metal-containing species phase in the platinum deposited in the carbon particles. For at least this reason, Maley et al. does not teach or suggest the claimed invention.

Accordingly, for all of the above reasons, this rejection should be withdrawn.

Rejection of claims 1, 3, 6, and 10 under 35 U.S.C. §102(e) over Dai et al.

At page 3 of the Office Action, the Examiner rejected claims 1, 3, 6, and 10 under 35 U.S.C. §102(e) as being anticipated by Dai et al. (U.S. Patent No. 6,528,020 B1). The Examiner alleged that Dai et al. describes a sensing apparatus comprising conductive modified particles (carbon nanotubes) having at least one organic group attached, such as an immobilized enzyme, to the particles. For the following reasons, this rejection is respectfully traversed.

The present invention relates to a sensor for detecting an analyte in a fluid, wherein said sensor comprises a layer comprising conductive modified particles. Dai et al., on the other hand, relates to carbon nanotube devices that are made up of either a single nanotube that bridges a space between two electrodes (see col. 4, lines 35 - 40 of Dai et al.) or a film that is made up of interconnected nanotubes formed *in situ* on a substrate and connected to electrodes (see col. 4, lines 41 - 57 of Dai et al.). Dai et al. does not teach the limitation of claim 1 of conductive modified particles as this term is commonly understood in the art with respect to carbon materials such as carbon black. The term "nanotubes" merely refers to a form of carbon material that has a cylindrical or tubular structure made up of graphitic layers. If nanotubes are capped on the ends, then they are in the form of particles; however, this is not the form of nanotubes that is described in Dai et al. Rather, the nanotubes described in Dai et al are either connected at each end to a catalyst island or are fused together to form a nanotube film of interconnected nanotubes. Neither of these structures meets the limitation of particles.

The Examiner's allegation at page 4 and page 16 of the Office Action that Dai et al. teaches modified conductive particles is incorrect and based on a mis-reading of Dai et al. Claim 1 of the present invention provides that the conductive modified particles may be carbon products that are modified by attaching organic groups. The Examiner notes that nanotubes are considered to be a carbon product. However, it does not logically follow from these premises that all nanotubes are particles. In fact, as discussed above, Dai et al. describes a particular form of nanotubes that are not in the form of particles. Accordingly, Dai et al does not teach or suggest any structure that includes a layer of conductive modified particles.

Moreover, Dai et al. does not teach or suggest conductive modified particles having an

organic group directly attached to the particles, as required by independent claim 1. Although Dai et al. describes a PMMA (polymethylmethacrylate)-covered nanotube film, this embodiment is clearly different from, and does not teach or suggest, conductive particles comprising a carbon product or colored pigment having at least one organic group attached directly to the particles. Further, in the description in Dai et al. of enzymes being attached to a nanotube film device, the attachment is through a thiol group that is applied to gold particles that are deposited on the nanotube film. Therefore, Dai et al. simply does not teach or suggest direct attachment of at least one organic group to conductive particles that are a carbon product or pigment.

Accordingly, this rejection should be withdrawn.

Rejection of claims 2, 22 - 26, 29 - 32, and 33 - 37 under U.S.C. §103(a) over Maley et al.

At page 5 of the Office Action, the Examiner rejected claims 2, 22 - 26, 29 - 32, and 33 - 37 under 35 U.S.C. §103(a) as being obvious over Maley et al. Regarding claims 2, 22 - 25, and 31, the Examiner alleged that Maley et al. teaches an electrochemical sensing apparatus comprising conductive modified particles such as electrically conducting carbon, or graphite powder particles having at least one organic group attached such as an immobilized enzyme, to the particles. The Examiner acknowledged that Maley et al. does not specifically describe an array of sensors, wherein the array comprises two or more sensors. However, the Examiner alleged that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. Moreover, the Examiner alleged that the use of a plurality of sensors arranged in an array configuration is well known in the art. The Examiner took the position that it would have been obvious to incorporate an array of sensors within the

sensing apparatus of Maley et al. in order to facilitate the detection and monitoring of a plurality of different chemical species within an environment. Regarding claims 22, 26, 29, and 32, the Examiner alleged that Maley et al. teaches the use of carbon black materials, and that these are well known in the art to be aggregated pigment materials. Regarding claim 30, the Examiner alleged that Maley et al. teaches that the carbon particles may further comprise a metal substrate layer coating comprising platinum. Regarding claims 33 - 37, the Examiner alleged that enzymes are proteinaceous materials composed of polymeric peptides well known in the art to comprise various functional organic groups, such as aromatic and ionic groups. For the following reasons, this rejection is respectfully traversed.

The arguments set forth above with respect to the earlier rejection in view of Maley et al. apply equally here. In particular, Maley et al. does not teach or suggest the structural limitations of a layer of conductive modified particles having a preexisting resistance that is altered in the presence of an analyte and an electrical measuring device that detects the alteration in the preexisting resistance. The statement made by the Examiner that Maley et al. teaches the structure recited in the claimed method is therefore clearly in error with respect to the claims. Moreover, there would not be any motivation to alter the structure of Maley et al. to meet these limitations since Maley et al. is directed to a completely different type of sensor, namely, one that uses an enzyme electrode that measures an electric current generated by electrons released by hydrogen peroxide generated from the degradation of glucose. Therefore, since Maley et al. does not teach or suggest the particular sensor of claim 1, Maley et al. does not teach or suggest an array that includes at least one of the sensors as required by claims 2, 19 - 26, 29 - 32, and 33 - 40. Therefore, this rejection should be withdrawn.

Rejection of claim 6 under 35 U.S.C. §103(a) over Maley et al. in view of Dai et al.

At page 6 of the Office Action, the Examiner rejected claim 6 under 35 U.S.C. §103(a) as being unpatentable over Maley et al. in view of Dai et al. The Examiner acknowledged that Maley et al. does not specifically teach the incorporation of carbon nanotubes for sensing. The Examiner alleged that Dai et al. teaches the use of carbon nanotubes in a biological sensor, wherein the biological molecules, such as an enzyme can be attached to the nanotube. The Examiner further alleged that Dai et al. recognizes that there is a need in the art for sensing devices that provide a significant, robust, and tunable response to a variety of chemical and biological species. In addition, the Examiner alleged that the disclosures of both Dai et al. and Maley et al. are directed to sensing devices for detecting glucose and that both of the sensors function in a similar manner based upon using an electrochemical response. The Examiner took the position that a person skilled in the art would have recognized the suitability of incorporating the teachings of Dai et al. with the sensing apparatus of Maley et al. for the intended purpose of facilitating the effective sensing operation of a biological sensor and that it would have been obvious to incorporate the use of a carbon nanotube, as taught by Dai et al. with the sensing apparatus of Maley et al. in order to facilitate detection. For the following reasons, this rejection is respectfully traversed.

The arguments set forth above with respect to Maley et al. and Dai et al. apply equally here. In particular, Maley et al. does not teach or suggest the structural limitations of a layer of conductive modified particles having a preexisting resistance that is altered in the presence of an analyte and an electrical measuring device that detects the alteration in the preexisting resistance.

Furthermore, Maley et al. does not teach or suggest any of the particular types of conductive modified particles as required in claim 6. As noted above, Dai et al. does not teach the limitation of conductive modified particles. The term "nanotubes" merely refers to a form of carbon material that has a cylindrical or tubular structure made up of graphitic layers. The fact that claim 6 of the present invention lists nanotubes as one of the types of conductive modified particles does not mean that all nanotubes are particles, as that term is commonly understood in the art with respect to carbon materials such as carbon black. As discussed above, in Dai et al., the nanotubes are not in the form of particles, but rather are either a single nanotube that bridges a space between two electrodes or a film that is made up of fused, interconnected nanotubes formed *in situ* between, and attached directly to, electrodes. Dai et al. does not teach or suggest nanotubes that are conductive modified particles and that have attached organic groups. Therefore the combination of Maley et al. and Dai et al. does not teach or suggest all of the limitations of claim 6. Therefore, this rejection should be withdrawn.

Rejection of claims 1 - 3, 6, 10, 12 - 24, 27, 31, and 33 - 40 under 35 U.S.C. §103(a) over Lewis et al. (U.S. Patent No. 5,571,401) in view of Dai et al.

At page 7 of the Office Action, the Examiner rejected claims 1 - 3, 6, 10, 12 - 24, 27, 31, and 33 - 40 under 35 U.S.C. §103(a) as being unpatentable over Lewis et al. (U.S. Patent No. 5,571,401) in view of Dai et al. Regarding claims 1 - 3, 6, 10, 22 - 24, 27 and 31, the Examiner alleged that Lewis et al. describes a sensing apparatus comprising a first and second sensor electrically connected to an electrical measuring apparatus, wherein the first sensor comprises a region of nonconducting organic polymer material and a region comprising conductive particles,

such as carbonaceous materials, and an electrical path through the regions of nonconducting material and conductive particles. The Examiner acknowledged that Lewis et al. does not specifically teach that the conductive modified particles include conductive particles having at least one organic group attached to the particles. The Examiner alleged that Dai et al. describes the use of carbon nanotubes in chemical sensors and mentions that there is a need in the art for sensing devices that provide a tunable response to a variety of chemical and biological species. The Examiner further alleged that Dai et al. describes that the nanotubes can be physically or chemically modified, so as to be tailored for a particular sensing application. The Examiner further alleged that Dai et al. teaches that sensing agents can be deposited onto the nanotubes so that sensitivity to a wide range of chemical species can be achieved and that Dai et al. teaches a sensing apparatus comprising conductive modified particles having at least one organic group attached, such as a mobilized enzyme, to the particles, and that, as evidenced by Dai et al., organic polymers can be attached or deposited onto the nanotubes and thereby serve as effective sensing agents. The Examiner took the position that it would have been obvious to incorporate the teachings of Dai et al. with the sensing apparatus of Lewis et al. Regarding claims 12, 13, 15, 16, 33, 34, 36, and 37, the Examiner alleged that Dai et al. teaches the incorporation of various polymers, such as polymethylmethacrylate or biomolecules such as enzymes, which are allegedly well known in the art to be proteinaceous materials comprising various functional groups. Regarding claims 14 and 35, the Examiner alleged that Dai et al. teaches the incorporation of a thiol functional group. Regarding claim 17, the Examiner alleged that Lewis et al. teaches that each sensor provides a different response for the same analyte with a detector that is operatively associated with each sensor. Regarding claim 18, the Examiner alleged that Lewis

et al. teaches that the sensing elements for each sensor are compositionally different from each other. Regarding claims 19 - 21 and 38 - 40, the Examiner alleged that Lewis et al. in view of Dai et al. teaches the structure recited in the claimed method, which, the Examiner alleged, merely recites the conventional operation of that structure and that the properties and functions of the structure are presumed to be inherent. The Examiner further alleged that Lewis et al. teaches that the method and apparatus essentially comprise a means for comparing the response with a library of responses to match the response in order to determine the presence of an analyte or the concentration of the analyte. The Examiner took the position that it would have been obvious to perform the method recited in the instant claims upon the apparatus of Lewis et al. in view of Dai et al. as the intended operation of that apparatus. For the following reasons, this rejection is respectfully traversed.

Lewis et al. describes sensors having conventional conducting and non-conducting materials arranged in a matrix of conducting and non-conducting regions. As acknowledged by the Examiner, the conductive region of Lewis et al. does not include a layer of conductive <u>modified</u> particles as required in the sensor of claim 1 of the present application.

The arguments set forth above with respect to Dai et al. apply equally here. In summary, Dai et al. does not teach or suggest any conductive carbon product that is in the form of <u>particles</u>. As discussed above, the nanotubes that are described in Dai et al. are either a single nanotube that bridges a space between two electrodes or a film that is made up of <u>interconnected</u> nanotubes. Since Dai et al. does not teach or suggest nanotubes that are in the form of particles, the apparatus of Lewis et al., which requires conductive <u>particles</u> cannot be combined with the single nanotube or nanotube film of Dai et al. to achieve the invention of claims 1 - 3, 6, 10, 12 -

24, 27, 31, and 33 - 40. The combination would not form a matrix of conductive and non-conductive regions such as described in Lewis et al.

Even if one skilled in the art were to combine Lewis et al. and Dai et al., the combination of the two references does not teach or suggest conductive particles having at least one organic group attached to the particles, wherein the conductive modified particles include carbon products having attached at least one organic group, colored pigments having attached at least one organic group, or combinations thereof. As discussed above, the combination of the two references does not teach or suggest that at least one organic group is directly attached to the particles. In fact, as stated above, the thiol group of Dai et al. is applied to the gold particles. Therefore, Dai et al. simply does not teach or suggest direct attachment of at least one organic group to the conductive particles that are a carbon product or pigment.

Therefore, the combination of the references does not teach or suggest the claimed invention. Accordingly, this rejection should be withdrawn.

Rejection of claims 25, 26, and 30 under 35 U.S.C. §103(a) over Lewis et al. in view of Dai et al. and further in view of Foulger et al.

At page 9 of the Office Action, the Examiner rejected claims 25, 26, and 30 under 35 U.S.C. §103(a) as being unpatentable over Lewis et al. in view of Dai et al. and further in view of Foulger et al. (U.S. Patent No. 6,315,956 B1). The Examiner alleged that Lewis et al. teaches the incorporation of carbon black, as a particulate conductive or conductive filler material within a matrix of nonconductive organic polymer material comprising the sensing material. The Examiner acknowledged that neither Lewis et al. nor Dai et al. specifically teach that the

conductive particles comprise carbon black having attached at least one organic group. The Examiner alleged that Foulger et al. describes the use of conductive filler materials comprising, *inter alia*, carbon black and carbon nanotubes, within an electrochemical sensor, in which the sensitivity and dynamic range of the electrochemical sensor is highly dependent on the conductive filler material. The Examiner further alleged that Foulger et al. teaches that the conductive filler material may be any suitable material exhibiting conductivity and should have a structure that results in an inherently high conductivity with an affinity to develop a strong network. The Examiner took the position that a person of ordinary skill in the art would have recognized the functional equivalence of carbon black and carbon nanotube materials, as a particulate conductive or filler material used in sensing applications and that it would have been obvious to substitute and incorporate the known equivalent carbon black material, as allegedly taught by Foulger et al. having an attached organic group, as allegedly taught by Dai et al., with the sensing apparatus of Lewis et al. in order to provide an effective sensing operation. Regarding claim 26, the Examiner alleged that it is well known in the art that carbon black is a pigment material. Regarding claim 30, the Examiner alleged that in Dai et al., the carbon nanotubes may be coated with metal particles, which impart sensitivity to a particular chemical species. The Examiner took the position that it would have been obvious to incorporate conductive particles comprising at least partially coated carbon black materials within the sensing apparatus in order to provide for optimal sensor operation for a particular sensing application. For the following reasons, this rejection is respectfully traversed.

The arguments set forth above with respect to Lewis et al. and Dai et al. apply equally here. In particular, as acknowledged by the Examiner, Lewis et al. does not teach or suggest a

sensor array in which a first sensor includes a region comprising conductive modified particles that are carbon black particles that have at least one organic group directly attached to the particles as required in claim 25 or colored pigments that have at least one organic group directly attached to the particles as required in claim 26 or partially coated carbon black as required in claim 30. Also as discussed above, Dai et al. does not teach or suggest any conductive carbon product that is in the form of particles. As discussed above, the nanotubes that are described in Dai et al. are either a single nanotube that bridges a space between two electrodes or a film that is made up of interconnected nanotubes.

Foulger et al. relates to an electrochemical sensor made from conductive polymer composite materials and methods of making same and describes that the composite material may include a conductive filler material. Although Foulger et al. contains the statement noted by the Examiner that the conductive filler may be "any suitable material exhibiting conductivity" and that it "should have a chemical structure which results in an inherently high conductivity with an affinity to develop a strong network," the only specific conductive fillers are conventional carbon black, graphite, metallic particles, intrinsically conductive polymers, carbon fiber, nanotubes, and mixtures thereof. Foulger et al. contains absolutely no suggestion that the conductive modified particles include carbon black particles that have at least one organic group directly attached to the particles as required in claim 25 or colored pigments that have at least one organic group directly attached to the particles as required in claim 26 or partially coated carbon black as required in claim 30. No discussion of carbon blacks having attached at least one organic group exists in Foulger et al. In fact, Foulger et al. merely states that the carbon black can be part of the polymer blend used to form the electrochemical sensor. Merely putting carbon

black in a polymer blend is not at all the same as attaching an organic group onto carbon black. There is no teaching or suggestion in Foulger et al. that any part of the polymer actually attaches onto the carbon black. Thus, Foulger et al. merely relates to a conventional polymer blend which includes a variety of components. Clearly, this is quite different from the claimed invention. Moreover, as discussed above, the single nanotube or nanotube film described in Dai et al. is not the functional equivalent of either nanotube particles or carbon black particles. Furthermore, Dai et al. does not describe organic groups that are attached directly to a nanotube, but only describes an enzyme that is attached to a nanotube through an intermediary or a metal film and a thiol group or a polymer coating over a nanotube film. Moreover, Dai et al. does not contain any teaching or suggestion to attach organic groups to particles.

At page 22 of the Office Action, the Examiner states that one cannot show nonobviousness by attacking references individually where rejections are based on combinations of references. In fact, the applicants' argument in this response, and in applicants' previous response, is that none of the references teaches or suggests one of the limitations of claims 25, 26 and 30, specifically, conductive modified particles having organic groups attached directly to the particles. Therefore, since none of the references individually teaches or suggests conductive modified particles having organic groups attached directly to the particles, the limitation is not taught or suggested by combining the references.

Therefore, the combination of the references does not teach or suggest the claimed invention. Accordingly, this rejection should be withdrawn.

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CONCLUSION

In view of the foregoing remarks, the applicants respectfully request the reconsideration of this application and the timely allowance of the pending claims.

If there are any fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 03-0060. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,

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